

**REMARKS**

Applicant has carefully reviewed the final Office Action mailed July 17, 2008 and the references cited therein and respectfully submit the following remarks. Claims 1 and 3-20 are currently pending. Claims 14-20 are new. The Examiner has rejected claims 1 and 3-13. In view of the following remarks, allowance of this application is most respectfully requested.

**I. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

The Examiner has rejected claims 1, 3-6 and 8-13 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Specifically, the Examiner states that:

Since applicants definition of “derivative” is opened ended, what is encompassed by “derivative” cannot be definitely determined.

Numerous compounds could possibly be derived from lecithin including simple elements like carbon and hydrogen.

Office Action of July 17, 2008 at page 2. Applicant respectfully disagrees with the Examiner’s position and respectfully submits that the claims are definite for at least the following reasons.

A claim to a chemical compound is not indefinite merely because a structure is not presented or because a partial structure is presented. Chemical compounds may be claimed by a name that adequately describes the material to one skilled in the art. *See Martin v. Johnson*, 454 F.2d 746, 172 USPQ 391 (CCPA 1972). A compound of unknown structure may be claimed by a combination of physical and chemical characteristics. *See Ex parte Brian*, 118 USPQ 242 (Bd. App. 1958). A compound may also be claimed in terms of the process by which it is made without raising an issue of indefiniteness. MPEP 2173.05(t).

The test for definiteness under 35 U.S.C. 112, second paragraph, is whether “those skilled in the art would understand what is claimed when the claim is read in light of the specification.” *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). If one skilled in the art is able to ascertain the meaning of the claim terms in light of the specification, 35 U.S.C. 112, second paragraph, is satisfied. The essential inquiry pertaining to the requirement for definiteness is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity. The fact that claim language may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Rather, acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification. MPEP 2173.05(b). Definiteness of claim language is analyzed, not in a vacuum, but rather in light of the content of the particular application disclosure, the teachings of the prior art; and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. MPEP 2173.02.

That the term “derivative” is not indefinite, is evidenced by the fact that over 45,000 patents have issued in the United States with the “derivative” as a claim term, many of which use the term to describe a chemical component within a composition or process. For example, U.S. Patent Nos. 7,470,781 (see claim 13 in which the substituent R<sub>6</sub> is a cholesterol derivative); 7,473,807 (see claim 1, which refers to a “carboxylic acid derivative”); 7,471,503 (see claim 9, which refers to “an organophosphorus acid or a derivative thereof.”); 7,470,539 (see claim 1, which refers to “a maleic anhydride derivative”); 7,468,151 (see claim 22, which refers to a “dextran or a dextran derivative”);

and 7,468,281 (see claim 22, which refers to “a cellulose derivative”), each recite the derivative of a particular chemical component in the claims that were allowed by the PTO.

Just as in each allowed patents referenced above, Applicant respectfully submits that one skilled in the art would be able to ascertain the meaning of the terms derivative in light of the specification and the knowledge of the skilled artisan. In evaluating the definiteness of claim language, the claim interpretation that would be given by one of ordinary level of skill in the art is an important factor. MPEP 2173.02. The term “derivative” is a common term that would be readily understood by a person of ordinary skill in the art. For example, Van Nostrand’s Scientific Encyclopedia provides the following definition for derivative:

**DERIVATIVE:** 1. A term used in organic chemistry to express the relation between certain known or hypothetical substances and the compounds formed from them by simple chemical processes in which the nucleus or skeleton of the parent substance exists. Thus phenol, aniline and toluene are derivatives of benzene, and many of the terpenes are derivatives of cymene. (emphasis added).

Also, Meriam-Webster’s Collegiate Dictionary, 10<sup>th</sup> edition, provides the following definition for derivative:

**derivative:** ... **4 a:** a chemical substance related structurally to another substance and theoretically derivable from it.

Thus, as evidenced by the above definitions, the term “derivative” has the well understood meaning to a person of ordinary skill in the art of a compound that is related to a parent substance by simple chemical processes and in which the core or skeleton of the parent substance is still recognizable, *i.e.*, the parent compound and its derivative are structurally related.

As is readily apparent from the use of the term “derivative” in the above referenced allowed patents and the definitions of derivative provided above, the assertion by the

Examiner that “simple elements like carbon and hydrogen” would be derivatives of lecithin is clearly not correct. Rather, a person of skill in the art would understand that a parent compound and its derivative are structurally related. Thus, a person of ordinary skill in the art would readily recognize that a derivative of lecithin (i) would be able to be prepared from lecithin by a simple chemical process, and (ii) would have a recognizable core skeleton of lecithin. Applicant respectfully submits that the meaning of the term “derivative” would be reasonably clear to a person of ordinary skill in the art and that the claims fully comply with the definiteness requirement of section 112.

## II. REJECTION UNDER 35 U.S.C. § 103

The Examiner has rejected claims 1 and 3-13 under 35 U.S.C. §103(a), as being unpatentable over Belzowski *et al.* (U.S. 6,207,207) and Domb (U.S. 5,188,837). Applicant respectfully submits that the presently claimed invention is patentable over Belzowski *et al.* and Domb for at least the following reasons.

The present invention is directed to a food additive in a granulate form comprising a plant natural product having a spherical surface, and a coating on the plant natural product. The coating comprises a lecithin and a lecithin derivative which is present in an amount greater than about 50 percent by weight of the coating. The food additives according to the invention can be readily eaten orally.

As the Examiner acknowledges, Belzowski *et al.* “does not teach lecithin, phosphatidyl serine, wax, thickness of coatings, and amounts of lecithin.” Office Action of July 17, 2008 at page 3. Belzowski *et al.* also do not teach or suggest the coating of a plant natural product having a spherical surface.

Domb is directed to an entirely different field than that of the present invention. The delivery system of Domb is a “microsuspension system” that contains “lipospheres, which

are solid, water-insoluble microparticle that have a layer of a phospholipid embedded on the surface.” Domb, Col. 2, lines 27-31 (emphasis added). As is readily evident from the term “micro” used by Domb, the delivery system provided by Domb is distinct from the presently claimed food additive in a granulate form. Rather, Domb is directed to “the area of controlled delivery systems, including pharmaceuticals.” Domb, Col. 1, lines 9-10.

In contrast to the presently claimed food additives in granulate form, Domb provides a “microsuspension system” comprised of microparticles that have a phospholipid layer embedded in their surface. Domb, Col. 1, lines 58-63. The microparticles are taught to be on the order of 5 to 250 microns in diameter. Domb, Col. 6, lines 10-15 (*also see* claim 1, in which the liposphere has an average particle size of between 0.3 and 250 microns). The phospholipid layer embedded in the surface of these very tiny microparticles is a single layer (*i.e.*, one molecule thick), as the hydrophobic side of the phospholipid is embedded in the outermost layer of the solid hydrophobic vehicle (core) and the hydrophilic side of the phospholipid forms the aqueous interface. Domb, Col. 6, lines 16-20; claim 1. Because the microparticles of Domb are so small (less than 250 microns), the single layer of phospholipid can disperse the liposphere in an aqueous medium to give a “microsuspension.” Domb, Col. 2, lines 48-54; Col. 2, lines 58-63; Col. 3, line 10.

Thus, the phospholipid layer and methods of Domb would be wholly unsuitable for use in the present invention. The single-molecule thick phospholipid layer of Dole is distinct from the coating of the present invention. It simply makes no sense for the claimed food additive in granulate form, which is comprised of a plant natural product having a spherical surface, to include the single-molecule thick layer of a phospholipid that is disclosed by Domb.

Thus, Domb does not teach or suggest the coating of a plant natural product having a spherical surface. As Domb is directed to a wholly difference field of endeavor than the claimed invention, there would be no motivation to combine Domb with Belzowski in an attempt to arrive at the presently claimed invention. Moreover, neither Belzowski *et al.* nor Domb teach or suggest a plant natural product having a spherical surface. Also, neither Belzowski *et al.* nor Domb teach or suggest the coating of such a plant natural product with a coating comprising at least one of lecithin and a lecithin derivative. Thus, any combination of Belzowski *et al.* and Domb would fail to arrive at the presently claimed invention.

In view of the foregoing comments, Applicant respectfully requests that the rejection under 35 U.S.C. §103 over Belzowski *et al.* and Domb be withdrawn.

#### IV. CONCLUSION

Applicant respectfully submits that the pending claims are in condition for allowance and requests that such action be taken. If for any reason the Examiner believes that prosecution of this application would be advanced by contact with the Applicant's attorney, the Examiner is invited to contact the undersigned at the telephone number below.

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Respectfully submitted,

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